510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: March 2, 2004

1. Company and Correspondent making the submission:

   Name – MEDITEC Co., Ltd.

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   Telephone – 82 31 707-2701

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   Contact – Mr. DongHyun Chang

   Internet – http://www.mediteco.co.kr

2. Device :

   Proprietary Name – Wrist Type Blood Pressure Monitor(MD-880B, MD-900T)

   Common Name – Noninvasive Blood Pressure Measurement System,

   Classification Name – System, Measurement, Blood Pressure, Noninvasive

3. Predicate Device :

   1) Omron Healthcare, Inc.

      HEM-630

      K001671(Decision Date - 06/30/2000)

   2) MEDITEC Co., Ltd.

      MD-770

      K992328(Decision Date - 07/21/1999)

4. Classifications Names & Citations :

   21CFR 870.1130, DXN, SYSTEM, MEASUREMENT, BLOOD-PRESSURE, NON-INVASIVE, Class2 Guidance document for the preparation of premarket notifications [510(k)'s] for Non-invasive blood pressure monitor guidance

5. Description :

MD-880B, MD-900T models are oscillometric systems intended for measurement of blood pressure and purse rate in a home care environment.

1) MD-880B : MD-880B employs the oscillometric method for measurement of blood pressure and heart rate. A cuff is wrapped around the wrist and inflates to a pressure sufficient to initially interrupt blood flow. As cuff pressure is gradually reduced, a sensor inside the cuff detects the small oscillations in pressure against the cuff produced by expansion and contractions of the arteries in the wrist in response to each heart beat. The amplitude of these pressure waves is measured to monitor changes in the character of blood flow and the corresponding cuff pressure at which these changes occur is detected. The systolic and diastolic pressure in millimeters of mercury, followed by the heart rate in beats per minute, is displayed as a numerical value on the LCD.

The cuff is automatically inflated by a built-in air pump(low noise) and selected inflation level by checking heart beat signal. The inflation is automatically activated in about 1 second after power on. The three-row, 9-digit LCD displays systolic pressure(upper 3-digits) and diastolic pressure(middle 3 digits) and heart rate(lower 3-digits). In addition, the date and time are displayed(8-digit).

MD-880B incorporates a constant air release valve to regulate deflation rate, within limits of 2 or 3 mmHg/sec to optimize measurement accuracy. The pressure measurement range is 20 to 285 mmHg. And keys are consisting of push-button switch instead of touch screen(MD-900T) for low cost model.

MD-880B is powered by two AAA-size batteries and are equipped with a circuit that will automatically cut off power after about 1 minutes of non-use to conserve battery charge.

2) MD-900T : MD-900T employs the oscillometric method for measurement of blood pressure and heart rate. A cuff is wrapped around the wrist and inflates to a pressure sufficient to initially interrupt blood flow. As cuff pressure is gradually reduced, a sensor inside the cuff detects the small oscillations in pressure against the cuff produced by expansion and contractions of the arteries in the wrist in response to each heart beat. The amplitude of these pressure waves is measured to monitor changes in the character of blood flow and the corresponding cuff pressure at which these changes occur is detected. The systolic and diastolic pressure in millimeters of mercury, followed by the heart rate in beats per minute, is displayed as a numerical value on the LCD.

The cuff is automatically inflated by a built-in air pump(low noise) and selected inflation level by checking heart beat signal. The inflation is automatically activated in about 1 second after power on. The three-row, 9-digit LCD displays systolic pressure(upper 3-

digits) and diastolic pressure(middle 3 digits) and heart rate(lower 3-digits). In addition, the date and time are displayed(8-digit).

MD-900T incorporates a constant air release valve to regulate deflation rate, within limits of 2 or 3 mmHg/sec to optimize measurement accuracy. The pressure measurement range is 20 to 285 mmHg.

MD-900T is powered by two AAA-size batteries and are equipped with a circuit that will automatically cut off power after about 1 minutes of non-use to conserve battery charge.

6. Indication for use :

Measuring Systolic and Diastolic blood pressure and pulse rates in adult patients with arm circumferences between 5¼ ~ 7½ inches using the oscillometric method

7. Comparison with predicate device :

MD-880B, MD-900T models have been compared with the automatically inflated Omron Healthcare model HEM-630 and Meditec model MD-770. The intended use of the 2 subject devices and the predicate devices is the same. The principle of operation(oscillometric measurement) is identical and there are no significant differences on operating features. It is concluded that there are no technologic differences between the subject and predicate devices that raise new questions concerning either safety or effectiveness.

8. Performance Data :

The measurement performances of the 2 MEDITEC systems have been evaluated in clinical studies conducted on accordance with ANSI/AAMI SP 10-1992 and found to comply fully with the accuracy criteria established in the standard. Safety and functional testing including electrical characteristics, mechanical and environmental integrity under various operating and storage conditions, high and low altitude performance, resistance to vibration and shock, life cycle testing, and intra-device variability has been performed with satisfactory results. The biocompatibility of cuff materials was evaluated favorably by TUV Product Service. Electromagnetic interference studies have been conducted by ONETECH Testing & Evaluation Laboratories and found to comply with international standards. Software validation have been performed and documented. It is concluded that the subject devices comply with all relevant safety and performance standards.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "Guidance document for the preparation of premarket notifications [510(k)'s] for NON-

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INVASIVE BLOOD PRESSURE (NIBP) MONITOR GUIDANCE" and based on the information provided in this premarket notification MEDITEC Co.,Ltd. concludes that MD-880B, MD-900T is safe and effective and substantially equivalent to predicate devices as described herein.

10. MEDITEC Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 5 2004

Meditec Co., Ltd.
c/o Mr. Chan Yo Won
Project Engineer
Underwriters Laboratories, Inc.
UL Conformity Assessment Services
2600 N.W. Lake Road
Camas, WA 98607-8542

Re: K041789
Trade Name: MD-880B, 900T
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 1, 2004
Received: July 2, 2004

Dear Mr. Won:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Neil R.P. Ogden for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041789

Indications for Use

510(k) Number(if known):

Device Name: MD-880B, 900T

Indications for Use:

Measuring Systolic and Diastolic blood pressure and pulse rates in adult patients with arm circumferences between $5\frac{1}{4}$~$7\frac{1}{2}$ inches using the oscillometric method

Nancy C. Brogdon for DRZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041789

Prescription Use_____ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)